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Use of a paper disposable cup as a spacer is effective for the first-aid management of asthma

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Abstract: *Objective:* There are many settings in which a spacer device is not available for the administration of bronchodilator. Therefore, we tested whether a paper disposable cup is as effective as a commercially produced spacer to administer bronchodilator. *Methodology:* Randomised controlled trial. 50 subjects aged 16–50 years who had wheeze and a greater than 10% decrease in FEV_1 after histamine inhalation test (HIT). Subjects were randomised to either the 150 ml paper disposable cup group (CUP) or the commercially produced spacer group (SPACER). Twenty minutes after 400μg salbutamol was administered FEV_1 was measured. The recovery index measured post-bronchodilator FEV_1 as a percentage of baseline FEV_1. Also, analysis of covariance tested whether recovery of FEV_1 was related to the magnitude of the fall following the HIT. *Results:* There were no statistically significant differences between CUP and SPACER groups in any characteristics. There was no difference for the recovery index (t_{48}= 1.14, P=0.26). Regression analyses showed that the relation between the magnitude of the fall in FEV_1 during the HITand the percent recovery was not different between the CUP and SPACER groups (t=−1.2, P<0.23). *Conclusions:* A paper disposable cup was effective for the reversal of mild to moderate bronchoconstriction. Therefore, a paper disposable cup can be used for the first-aid management of asthma when there is concern about cross-infection and a commercially produced spacer is not available.

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INTRODUCTION

The administration of bronchodilator is essential for the first-aid management of an asthma attack. However, people who have asthma do not always carry a bronchodilator with them and may unnecessarily go without bronchodilator in such situations. Under these circumstances people who have asthma should be encouraged to use bronchodilator belonging to another person or available in a first-aid kit. A number of guidelines recommend the use of a commercially produced spacer device with a pressurised metered dose inhaler (pMDI) for the management of an asthma attack (1,2).

Concern has been raised about the theoretical possibility of cross-infection between users of spacers in settings such as schools, universities, sporting clubs and entertainment venues. The New South Wales Department of Health has issued a policy regarding infection control (3). The policy states that if a spacer is to be used by more than one person it must undergo disinfection by pasteurisation in a domestic dishwasher or by arrangement with a local hospital. It is unlikely that non-clinical settings where the first-aid management of asthma is provided are equipped, or have staff who are trained and feel competent, to disinfect spacers appropriately after use. This concern has the potential to discourage the use of any bronchodilator other than that belonging to the person having an asthma attack, which would mean less than optimal asthma management.

The aim of this study was to test the effectiveness of using a paper disposable cup as a spacer for the delivery of bronchodilator. The advantage of using a paper disposable cup is that it is readily available, inexpensive and, because it is a single-use device, will eliminate cross-infection. A previous study has shown equivalence in a clinical setting with children who had moderate-to-severe bronchoconstriction(4). We conducted a randomised controlled trial to test the hypothesis, that in adults the administration of bronchodilator through a paper disposable cup is just as effective for the reversal of mild-to-moderate bronchoconstriction as the administration of bronchodilator through a commercially produced spacer.

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METHODS

A total of 50 adult subjects were enrolled. The three criteria for inclusion in this study were (1) any person aged 16 years or older and (2) who had a history of wheeze and (3) who had a decrease in FEV_1 greater than 10% after the histamine inhalation test (HIT)(5). Subjects who met the inclusion criteria were consecutively enrolled into this study. All subjects gave their consent to be involved in this study and the Human Ethics Committee of the University of Sydney approved the protocol.

A self-administered questionnaire was used to collect data about asthma, medication use, smoking, and demographics such as age and sex.

Randomisation and masking

A random number chart was used to generate an allocation list. Allocation was concealed within consecutively numbered sealed envelopes that contained the word CUP or SPACER. After completion of the HIT, eligible subjects were randomly assigned to one of the two treatment groups. An investigator who did not perform the spirometry determined subject allocation by opening the next consecutive envelope in the series. Subjects were then taken to another room to administer the bronchodilator. Different investigators performed the spirometry and the administration of bronchodilator to ensure that the investigator who performed spirometry was blinded to group allocation.

CUP group

A 150 ml paper disposable cup was used and a cross was cut in the base of the cup. The Ventolin pMDI (100 μg salbutamol per actuation) was inserted through this opening into the base of the cup. The cup was placed within 5 cm of the front of the subject's face and the investigator's hand was placed over the opening of the cup. The pMDI was actuated once, the subject was told to breathe out and then the investigator's hand was removed from the opening of the cup and the subject inhaled deeply. The subject was told to hold their breath for up to 10 s and then to breathe out. The investigator then moved the cup to the side of the subject's face, to ensure that the subject did not breathe into the cup. A new cup was used for each subject. The cycle took approximately 15 s to complete and was repeated four times within a minute.

SPACER group

A Volumatic spacer with a Ventolin pMDI was used in this arm of the study. The pMDI was actuated once into the spacer, the subject was told to breathe out and then place their lips around the mouthpiece and then to inhale deeply. To prevent cross-infection, a small cardboard mouthpiece was placed over the Volumatic mouthpiece. The subject was told to hold their breath for up to 10 s and then breathe out. The cycle took approximately 15 s to complete and was repeated four times within a minute.

Statistical analyses

A recovery index was used as the outcome measure to determine the effectiveness of the use of a paper disposable cup as a spacer. The recovery index measured post-bronchodilator FEV_1 as a percentage of baseline FEV_1 and was calculated for each group. The disposable cup was considered as effective as the spacer if the mean recovery index was within 10% of the spacer. Sample size calculations estimate 28 subjects are needed in each group for power = 80% and alpha = 0.1 when SD is 1.5%.

Statistical analyses were performed with the statistical program SAS (version 6.22, Cary, NC: SAS Institute Inc). Data were compared using mean values for normally distributed variables and medians for non-normally distributed variables. Response dose ratio (RDR) was log-transformed to test for normality. The CUP and SPACER groups were compared using a two-sample *t*-test for normally distributed variables and a Wilcoxon non-parametric test for non-normally distributed variables.

Percent change in FEV_1 after bronchodilator was plotted against per cent change in FEV_1 after challenge and the regression line for each group calculated. Analysis of covariance was used to test for a significant difference between the regression slopes of the two groups.

RESULTS

A total of 50 subjects took part in this study. There was no significant difference in number of males, smokers, diagnosed asthma, using asthma medications or mean age, baseline % predicted FEV_1 or baseline FEV_1 between the CUP and SPACER groups. No subjects were randomised and then withdrawn from the study due to extreme breathlessness or wheezing after being given bronchodilator by either method.

The results following administration of histamine and bronchodilator are shown in Table 1. After histamine was administered there was no statistically significant difference between groups in the mean decrease in FEV_1, median RDR or the median time between administering bronchodilator and measuring the effect on FEV_1. A total of 64% of subjects in the CUP group and 72% of subjects in the SPACER group had a decrease in FEV_1 of greater than or equal to 20% after administration of histamine.

After the bronchodilator was administered there was no difference in the recovery index, which was used to determine the effectiveness of each of the methods.

Table I. Characteristics of the CUP and SPACER groups after administration of histamine and bronchodilator

	CUP group $n = 25$	SPACER group $n=25$	P value
After administration of histamine			
Mean decrease in FEV_1 (%) (SD)	20% (6.5)	23% (6.7)	0.14
Median RDR (%fall FEV_1/μmol) (IQR)	18.6 (57.3)	15.8 (26.8)	0.56
Median time to reversal FEV_1 (min) (IQR)	18.0 (12.0)	18.0 (11.0)	0.31
After administration of bronchodilator			
Mean Recovery Index (%) (SD)	98% (6)	100% (6)	0.26

After bronchodilator, the mean FEV_1 returned to 98% in the cup group of baseline and returned to 100% of baseline FEV_1 in the SPACER group (P=0.26). The mean and 95% confidence interval around the CUP recovery index was 98% (95% CI 96%, 100%). This result demonstrates equivalence between the two devices because the upper and lower limits of the CUP confidence interval is within 10% of the SPACER recovery index reflecting equivalence.

Regression analysis was performed to examine whether the relation between the percent change in FEV_1 after bronchodilator to the percent change in FEV_1 after challenge was different for each of the CUP and SPACER groups. This analysis showed that the difference between regression slopes for the CUP and SPACER group was not statistically significantly different ($t=-1.2$, $P<0.23$).

DISCUSSION

We found that a disposable paper cup is equally as effective as a commercially produced spacer for the reversal of mild-to-moderate bronchoconstriction in adults. The recovery index showed similar changes after bronchodilator administration whether by paper disposable cup or by a commercially produced spacer.

In this study both selection and observer bias was minimised. The subjects were reliably randomised to each of the treatment groups and the study had enrolled adequate sample size to be able to test for a difference between groups. No subjects were excluded from the study because of discomfort or worsening bronchoconstriction.

We attempted to replicate a 'real life' situation by using subjects who had various degrees of bronchoconstriction. We also used the dosage of bronchodilator (400 μg salbutamol) recommended by the National Asthma Council of Australia and taught in First Aid courses for the management of asthma. This study complements other studies by showing that for mild-to-moderate bronchoconstriction both methods of administration were equally effective for reversing bronchoconstriction.

School and sports centre staff and occupational first aiders may feel reluctant to administer another person's bronchodilator, or to use a communal use spacer because of government infection control policies. Furthermore, spacer devices require maintenance that may not occur in the hands of untrained non-medical personnel. A study of paediatricians in training demonstrated that even this group had variable understanding of the use and maintenance of the spacer device(6). Adults who have asthma may themselves be reluctant to use bronchodilator when they are concerned about the possibility of becoming infected with a communicable disease. We do not recommend the use of the disposable paper cup in settings where adult patients have access to their own pMDI or to a disinfected commercially produced spacer. However, in non-clinical settings where there is concern about theoretical cross-infection, the use of a disposable paper cup is an effective and hygienic alternative for the first-aid management of asthma.

The issue of the time course of natural recovery after the HIT is an important consideration. Cartier *et al*. measured the duration of the plateau period, which is the period immediately after administration of histamine during which time there is minimal recovery in FEV_1 (7). In their study, in which a similar dose of histamine to our study was used, the plateau period lasted for a mean of 16.8 min, range 4–37 min. After the plateau period recovery proceeded with some subjects requiring 90 min to recover from their bronchospasm. Similarly, a study of adults reported by Mathé *et al*. showed that the induction of bronchospasm might last from 15 to 30 min (8). In children, Gerritsen *et al*. showed that natural recovery time was related to the dose of histamine administered and the degree of bronchoconstriction caused (9). In their study, similar to this study in terms of dose of histamine administered and degree of bronchoconstriction caused, they reported that after 15 min only 18% of children's FEV_1 had recovered to within 95% of their baseline level. Furthermore, at 30 min post-challenge just over half of their subjects had recovered to within 95% of their baseline level. These studies give us confidence that in

our study, the improvement in FEV_1 after administration of bronchodilator was attributable to the effectiveness of the devices delivering the bronchodilator and not due to natural recovery.

The use of a commercially produced spacer device and pMDI reflects best practice for the first-aid management of asthma and we do not recommend the use of a disposable paper cup where one is available. However, concern is increasing about the risk of infection, and subsequent litigation, from first aid provided in non-clinical settings. This study shows that management guidelines can be modified to include the use of a disposable paper cup in settings where there is concern about cross-infection and where a casualty does not have their own pMDI or access to a clean commercially produced spacer device for the first aid management of an asthma attack.

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